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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,848	12/04/2001	Markus Haller	P-8572.00	7830

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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,848	HALLER, MARKUS	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *30-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 47-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-29 and 46-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boydman (USPN 5,069,668) in view of Fischell (USPN 4,731,051).

It is noted that the means plus function recitations in claims 46-49 are being interpreted as such. It is assumed that applicant has invoked 112 6th paragraph.

Regarding claims 1-4 and 14-16, Boydman discloses a method for activating a drug delivery system that includes maintaining a timer to time a lock out interval (see 5:18-26; 10:67-11:3 and # 150 in figure 2), rejecting a user request to activate the delivery system prior to expiration of the lockout interval (see 11:3-10), activating the drug delivery system in response to a user request received after expiration of the lockout interval (see figure 2 flowpaths 122b,124a,124b,124c and 114) and restarting the lockout interval upon activating the system (see figure 2 element 150 resets/sets the lockout timer in response to or after the dosing pathway has been activated). Activating or activation includes dispensing a bolus (see figure 2 element 114) that is maintained in a reservoir of the system. If the user requests a bolus administration during a lockout interval than the bolus amount is adjusted to zero bolus. The system also has a continuous infusion pathway (106) which is adjusted by the number of bolus requests made by the user over a period of time. See 10:40-66.

Regarding claims 22-26, it is considered inherent that the device includes a computer readable medium with instructions for carrying out the above. The medium is required and cannot be omitted for proper functioning of the device as disclosed.

Regarding claims 5-13,17-21,27-29,46-53 Boydman fails to teach an external activation device in conjunction with an implantable drug delivery system

However, Fischell discloses an external activation device and implantable pump. See figure and 3:15+. The activation device limits the amount of drug the patient can administer.

At the time of the invention, it would have been obvious to incorporate the external activation device and pump of Fischell into the method of Boydman. Both devices are analogous in the art of subcutaneous drug delivery. Additionally, the motivation for the combination would have been in order to enable the system and method of Boydman to be used with an ambulatory patient or one that desires free range of movement such as an active adult or child thereby enhancing the patient's quality of life. Enhancing patient quality of life is a well known advantage in the art and well known by one skilled in the art.

Response to Arguments

Applicant's arguments filed 9/8/2005 have been fully considered but they are not persuasive.

Applicant begins by arguing in general that neither Boydman nor Fischell teach the claimed invention. See remarks page 13 lines 8-16. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642

F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Boydman in view of Fischell would not result in the claimed invention. See remarks page 14 lines 12-14. See below for breakdown of the claims in view of the prior art rejection.

Applicant argues that there is no motivation for the combination of the references. See remarks page 14 line 14-18. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there is both motivation in the prior art itself and in the knowledge generally available to one of ordinary skill in the art. The Boydman reference itself teaches only a method for administering a drug and does not teach a specific device for carrying out that method. See Boydman 6:35-41. Boydman specifically states that the invention is "a method that can be carried out as by utilizing a wide variety of combinations and arrangements of hardware of a type and kind that are readily understood by those skilled in the art". Fischell teaches such a hardware that could carry out the method as taught by Boydman. Additionally, one skilled in the art would recognize that the hardware (implantable pump and external control unit) of Fischell is portable and would enable a patient freedom of movement if requiring long term medication, e.g. analgesia post orthopedic surgery.

Applicant then addresses sets of claims and how the prior art does not teach certain limitations of the claims. Applicant argues that Boydman does not teach an implantable drug delivery system but instead teaches an external infusion pump. Attention is drawn to the disclosure of Boydman which states that the external infusion pump shown in figure 1 is not part of the invention. Furthermore, the combination of Boydman in view of Fischell is relied on for the teaching of the implantable pump. See rejection above. Both the implantable pump and external activation device of Fischell are incorporated into the method of Boydman.

Applicant argues that Fischell does not teach the lockout interval. Fischell is not relied on for the lockout interval. See Boydman figure 2 element 150 for the lockout interval.

Applicant argues that Boydman does not teach adjusting the bolus amount in response to a user request. When the user requests a bolus during the lockout interval, for all intents and purposes, the bolus amount is adjusted to zero. See above rejection.

Regarding the arguments to claims 5,17,19,27,47 and 51, applicant addresses the references individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams
December 7, 2005